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| INFORMATION DISCLOSURE STATEMENT Address to: Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 | Attorney Docket | LIFE-037 |
| | First Named Inventor | Pugh, Jerry T. |
| | Confirmation Number | 5894 |
| | Application Number | 10/029,525 |
| | Filing Date | December 21, 2001 |
| | Group Art Unit | 3653 |
| | Examiner Name | NOLAND, KENNETH W. |
| | Title: | <i>"TEST DEVICE WITH MEANS FOR STORING AND DISPENSING DIAGNOSTIC STRIPS"</i> |

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. A Form SB08 (substitute for form 1449) listing the reference accompanies this paper. Applicants would appreciate the Examiner initialing and returning the form to indicate that the reference has been reviewed and made of record.

More specifically, the Applicant is submitting photographs and a description of a glucose monitoring system (the "System") that Applicant has been made aware of. The System (brand name "INTEGRA") was manufactured by Apprise, Inc., a company that is no longer in business. Reasonable efforts have been made by Applicant to find information about the INTEGRA system. However, Applicant has been unable to locate any documentation, including any product literature, relating to the INTEGRA system. However, a search of the U.S. Food & Drug Administration's ("FDA") website, and more specifically the FDA's 510(k) Premarket Notification Database accessed online via the world wide web, has uncovered a premarket notification (510(k)) summary relating to the INTEGRA Blood Glucose Monitoring System, a copy of which is herewith included. The premarket notification (510(k)) summary shows a "Date Received" of May 2, 1989 and a "Decision Date" of August 3, 1989. Furthermore, Applicant has been unable to verify specific dates relating to public knowledge of the System. However, Applicant believes that the INTEGRA system was in development at least as early as 1989, as evidenced by the 510(k) summary sheet, and was shown at a tradeshow in the early 1990's.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one of the above references constitutes prior art to the present application within the meaning of 35 U.S.C. §102.

Applicant(s) hereby petition for the consideration of this Information Disclosure Statement.

Att'y Dkt. No.: LIFE-037
USSN: 10/029,525

As applicants have not yet received a first Action on the merits, no fee is believed to be required for filing this Disclosure Statement. If, however, the PTO finds that for some reason a fee is due, our Deposit Account No. 50-0815, Order No. LIFE-037 may be charged thereon.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 9/17/03

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